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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,249	06/25/2003	Leonardus H.T. Van der Ploeg	20561YDA	3677
210	7590	03/02/2006	EXAMINER	
MERCK AND CO., INC			FALK, ANNE MARIE	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07065-0907			1632	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/603,249	VAN DER PLOEG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 30-32 and 36-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 30-32 and 36-57 are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

## **DETAILED ACTION**

The preliminary amendment filed June 25, 2003 has been entered. Claims 1-29 and 33-35 have been cancelled.

Accordingly, Claims 30-32 and 36-57 remain pending in the instant application.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 30-32, drawn to a transgenic mouse comprising an altered MC-3R gene and further comprising a non-native MC-3R gene, classified in class 800, subclass 18.
- II. Claims 36-43, drawn to a transgenic animal having an altered MC-3R gene and an altered MC-4R gene and cells derived from the transgenic animal, classified in class 800, subclass 13.
- III. Claims 44-46, drawn to a transgenic mouse having an altered MC-3R gene, an altered MC-4R gene, a non-native MC-3R gene, and a non-native MC-4R gene, classified in class 800, subclass 18.
- IV. Claims 47, 48, and 50-53, drawn to a method for determining whether a substance is capable of binding to MC-3R, a method for determining whether a substance is capable of activating MC-3R and regulating body weight, a method for determining whether a substance is a potential agonist or antagonist of MC-3R and regulates body weight, and a method for determining whether a substance is capable of binding to MC-3R and regulating body weight, classified in class 435, subclass 4.
- V. Claim 49, drawn to a method of identifying a substance which modulates MC-3R receptor activity and regulates body weight, classified in class 435, subclass 4.

- VI. Claims 54-56, drawn to a method of identifying agonists of MC-3R which regulate body weight and a method of identifying antagonists of MC-3R which regulate body weight, classified in class 435, subclass 4.
- VII. Claim 57, drawn to a method of selecting for a compound which shows *in vivo* efficacy for modulation of MC-3R and regulation of body weight, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct, one from the other, because the inventions are drawn to distinct transgenic animals. Each transgenic animal is made using different starting materials and each would be expected to have a unique phenotype. The transgenic animals are not obvious variants. Thus, one transgenic animal would not be considered obvious over any of the others. Thus, the inventions of Groups I-III are drawn to mutually exclusive compositions that are patentably distinct, each from the other.

Inventions I-III and IV-VII are patentably distinct because the inventions are drawn to compositions and methods that are not disclosed as being used together. The transgenic animals of the inventions of Groups I-III are not required for practice of the methods of the inventions of Groups IV-VII. Thus, the compositions of the inventions of Groups I-III are patentably distinct from the methods of the inventions of Groups IV-VII.

Inventions IV-VII are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. For example, the method of the invention of Group IV requires the use of a cell that has been genetically modified to express MC-3R, whereas the method of the invention of Group VI requires the use of a cell that has been genetically modified to express MC-3R and a promiscuous G-protein.

These are substantially different starting materials and the method steps measure different effects. Thus, the methods of the inventions of Groups IV-VII are patentably distinct, each from the other.

Each of the inventions of Groups I-VII requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the inventions of Groups I-III require consideration of issues relating to the utility of the transgenic mouse as claimed, whereas the invention of Groups IV-VII do not, but rather require consideration of issues relating to the utility and enablement of the screening methods as claimed. The utility of a transgenic mouse would be quite different from the utility of screening methods. Furthermore, the searches for the inventions of Groups I-VII are not coextensive. For example, a search for the knockout/mutant mouse of the invention of Group I would not necessarily identify art teaching the structurally distinct knockout/mutant mice of Groups II or III. Additional searching would be required to cover the full scope of the inventions of Groups II-VII and additional examination would be required to address all the issues relevant to Groups II-VII. Thus, search and examination of all 7 inventions in a single patent application constitutes a serious burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

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inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday from 10:00 AM to 8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER